Reconsideration of the application is respectfully requested.

I. AMENDMENT

In the Claims:

Please cancel claims 64, 110, and 111, without prejudice or disclaimer.

Please amend the claims as follows:

91. (Twice amended) A process of screening a substance for its ability to specifically bind to an opioid receptor, said process comprising the steps of:

a) expressing a recombinant opioid receptor polypeptide encoded for by a nucleic acid sequence comprising at least 30 contiguous bases of SEQ ID NO:1;

b) contacting said substance with the opioid receptor polypeptide; and

c) detecting the ability of said substance to specifically bind to said opioid receptor polypeptide.

97. (Twice amended) A process of screening a substance for its ability to specifically bind to an opioid receptor, said process comprising the steps of:

a) expressing a recombinant opioid receptor polypeptide encoded for by a nucleic acid sequence comprising a segment consisting of 30 contiguous bases of SEQ ID NO:11;

b) contacting said substance with the opioid receptor polypeptide; and

c) detecting the ability of said substance to specifically bind to said opioid receptor polypeptide.

98. (Twice amended) The process of claim 97, wherein said opioid receptor polypeptide is encoded for by a nucleic acid sequence comprising a segment consisting of 40 contiguous bases of SEQ ID NO:11.

99. (Twice amended) The process of claim 98, wherein said opioid receptor polypeptide is encoded for by a nucleic acid sequence comprising a segment consisting of 50 contiguous bases of SEQ ID NO:11.

100. (Twice amended) The process of claim 99, wherein said opioid receptor polypeptide is encoded for by a nucleic acid sequence comprising a segment consisting of 75 contiguous bases of SEQ ID NO:11.

101. (Twice amended) The process of claim 100, wherein said opioid receptor polypeptide is encoded for by a nucleic acid sequence comprising a segment consisting of 100 contiguous bases of SEQ ID NO:11.

102. (Twice amended) The process of claim 101, wherein said opioid receptor polypeptide is encoded for by a nucleic acid sequence comprising a segment consisting of 680 contiguous bases of SEQ ID NO:11.

109. (Twice amended) A process of isolating a substance with an ability to act as a specific agonist of a kappa opioid receptor, said process comprising the steps of:

a) providing an opioid receptor polypeptide comprising the second extracellular loop and encoded for by a nucleic acid sequence comprising a segment consisting of 60 contiguous bases of SEQ ID NO:11;

b) contacting said opioid receptor polypeptide with a composition comprising said substance;

c) detecting the ability of said substance to interact as an agonist with said opioid receptor polypeptide; and

d) isolating said substance if the ability of said substance to specifically bind to the opioid receptor polypeptide is detected.

112. (Twice amended) The process of claim 111, wherein said opioid receptor polypeptide is encoded for by a nucleic acid sequence comprising a segment consisting of 75 contiguous bases of SEQ ID NO:11.

113. (Twice amended) The process of claim 112, wherein said opioid receptor polypeptide is encoded for by a nucleic acid sequence comprising a segment consisting of 100 contiguous bases of SEQ ID NO:11.

114. (Twice amended) The process of claim 113, wherein said opioid receptor polypeptide is encoded for by a nucleic acid sequence comprising a segment consisting of 680 contiguous bases of SEQ ID NO:11.

115. (Amended) A process of screening a substance for its ability to specifically bind to an opioid receptor comprising:

a) expressing either (1) a recombinant opioid receptor polypeptide encoded for by a nucleic acid sequence comprising at least 30 contiguous bases of SEQ ID NO:1 or (2) a recombinant opioid receptor polypeptide comprising the second extracellular loop and encoded for by a nucleic acid sequence comprising a segment consisting of 60 contiguous bases of SEQ ID NO:11;

b) contacting said substance with the opioid receptor polypeptide; and

c) detecting the ability of said substance to interact with said opioid receptor polypeptide.

121. (Amended) The process according to claim 115, wherein the opioid receptor polypeptide is a kappa opioid receptor polypeptide having the sequence of SEQ ID NO:2 or comprising a segment consisting of SEQ ID NO:12.

124. (Amended) A process of isolating a substance with an ability to act as a agonist of a kappa opioid receptor comprising:

a) providing a recombinant opioid receptor polypeptide that includes the second extracellular loop and that is encoded for by a nucleic acid sequence comprising at least 30 contiguous bases of SEQ ID NO:1 or a segment consisting of SEQ ID NO:11;

b) contacting said opioid receptor polypeptide with a composition comprising the substance;

c) detecting the ability of the substance to interact as an agonist with the opioid receptor polypeptide; and

d) isolating the substance if an ability of the substance to interact with the opioid receptor polypeptide is detected.

129. (Amended) A process of screening a substance for its ability to act as an agonist of a kappa opioid receptor comprising:

a) expressing either (1) a chimeric recombinant opioid receptor polypeptide comprising a portion of the second extracellular loop and encoded for by a nucleic acid sequence comprising at least 30 contiguous bases of SEQ ID NO:1 or (2) a chimeric recombinant opioid receptor polypeptide comprising the second extracellular loop and encoded for by a nucleic acid sequence comprising a segment consisting of 60 contiguous bases of SEQ ID NO:11;

b) contacting said substance with the opioid receptor polypeptide; and

c) detecting the ability of the substance to interact as an agonist with the opioid receptor polypeptide.

II. RESPONSE TO OFFICE ACTION

A. Status of the Claims

The Office Action dated January 30, 2001 indicates that claims 97-136 are rejected and claims 91-96 are allowable. The Examiner notes in the Office Action that claim 64 appears to be pending. Claim 64 was not expressly cancelled in the previous response because that claim was not addressed in any of the rejections; however, Applicants cancel it herein. In addition, claims 110 and 111 are cancelled , and claims 91, 97-102, 109, 112-115, 124, and 129 are amended. Support for the amendments can be found on page 21, lines 22-24; page 23, lines 1-14; page 25, lines 12-19; page 28, lines 30-34; and page 127, lines 1-4. A marked up copy of the amendments is attached as Appendix A. Thus, claims 97-109 and 112-136 are the subject of this response. A clean copy of the pending claims should the amendments be entered is attached as Appendix B.

B. The Specification Adequately Describes Claims 97-102 and 109-114

The Office Action rejects claim 97-102 and 109-114 under 35 U.S.C. § 112, first paragraph, as lacking a written description. As argued previously, the application provides sequence information to indicate the Applicants were in possession of SEQ ID NO:11 at the time the application was filed. Patent law does not require applicants to limit specifically their invention only to embodiments reduced to practice, which is what the arguments in the Office Action suggest. Applicants have proposed amendments that fully comply with the written description requirement and patent law. Applicants respectfully request the rejection be withdrawn.

C. Claims 91-102 and 109-114 Have Been Amended to "Specifically Binds to"

Claims 91-102 and 109-114 were rejected under 35 U.S.C. § 112, and it was suggested that "interact with" be replaced with "specifically bind to." Applicants appreciate the Examiner's suggestion, which has been adopted. Independent claims 91 and 109 have been amended. Accordingly, Applicants respectfully request that this rejection be withdrawn.

D. Claims 103-114 and 129-135 Are Enabled

The Action rejects claims 103-114 and 129-135 under 35 U.S.C. 112, first paragraph. The Action states that a limitation to the second extracellular loop is not recited in the claims. However, claim 103 specifically recites a "second extracellular loop," which is described by amino acid sequence in the specification at page 96. "[C]laims are to be read in view of the specification of which they are a part." *Young Dental Mfg. Co. v. Q3 Special Prods., Inc.* 42 U.S.P.Q. 1589 (Fed. Cir. 1997). Thus, there is no need to amend claim 103 to recite particular amino acids that constitute the second extracellular loop.

As for claim 129, Applicants contend that the specification indicates that in preferred embodiments, a kappa opioid receptor polypeptide comprises "*a portion of a second extracellular loop* of the kappa opioid receptor polypeptide" because this region has been shown to have the binding site for kappa receptor-specific agonists. Specification at page 21, lines 21-32. Therefore, the specification indicates that Applicants were contemplating using all or part of the second extracellular loop in a preferred embodiment, and the law is clear that claims need not be limited to preferred embodiments.

Applicants have amended the claims to recite a "portion of the second extracellular loop." With respect to enablement, Applicants contend that it would not require undue experimentation

to determine which portion of the second extracellular loop was required for kappa-specific agonist binding. The second extracellular loop is only 18 amino acids long, and at the time the application was filed, mutagenesis procedures were well known to those of ordinary skill in the art (some procedures are disclosed in the application, for example, on pages 43-44, describing site-directed mutagenesis and on pages 148-49, describing generation of chimeric constructs). The skilled artisan could have readily employed mutagenesis techniques, including site-directed mutagenesis (described in Sambrook, 1989, which is specifically incorporated by reference) to alter this region. That person could then determine which portions of the second extracellular loop were required for agonist binding based on the specification, which teaches various binding assays and how to determine which regions of a polypeptide are involved in agonist binding. All of this could be done using only routine experimentation. "The specification must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" MPEP 2164.08 (citing *In re Wright*, 999 F.2d 1557, 1561, 27 U.S.P.Q. 1510, 1513 (Fed. Cir. 1993)). Accordingly, the claim, as amended, is fully enabled by the specification. Applicants respectfully request that this rejection be withdrawn.

E. Conclusion

With respect to the outstanding rejections, Applicants believe that the present document is a full and complete response to the referenced Official Action. In conclusion, Applicants submit that, in light of the foregoing remarks, the present case is in condition for allowance and such favorable Action is respectfully requested. Should the Examiner have any further questions or comments, or believe that certain clarifications might more readily progress the present

application to issuance, a telephone call to the undersigned Applicants' representative at (512) 536-3081 is earnestly solicited.

Respectfully submitted,

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